IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	David J. Yonce et al.	Examiner: Frances Oropeza
Serial No.:	10/723,254	Group Art Unit: 3766
Filed:	November 26, 2003	Docket No.: 279.628US1
Customer No.: 45458		Confirmation No.: 6063
Title:	MORPHOLOGY-BASED DIAGNOSTIC MONITORING OF ELECTROGRAMS BY IMPLANTABLE CARDIAC DEVICE	

REPLY BRIEF UNDER 37 C.F.R. § 41.41

Mail Stop Appeal Brief - Patents
Commissioner for Patents
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This Reply Brief is filed in response to the Examiner's Answer (hereinafter "Answer"), mailed on July 9, 2009, and supplements the Appeal Brief filed by the Appellant on January 21, 2009. If necessary, please charge any additional fees or credit overpayments to Deposit Account No. 19-0743.

REMARKS

Appellant has reviewed the Answer, and believes the statements in the original Appeal Brief remain accurate and compelling. In responding to the Answer, Appellant respectfully maintains that the Appeal Brief, which is hereby incorporated by reference and reasserted in response, overcomes the original grounds of rejections.

Before addressing the specific remarks made by the Examiner in the Answer, Appellant makes the following general comments. .Independent claims 1 and 11 basically recite systems for computing and displaying electrograms of a patient in a manner that shows how the morphology of the electrograms change over time or with respect to heart rate, respectively. Such computed and displayed electrograms are referred to as representative electrograms, where a representative electrogram represents either a particular time period or a particular heart rate range. The Levine reference does not disclose anything even remotely similar to what has just been described, and the Examiner does not assert otherwise. Instead, it appears that the Examiner attempts to argue that Levine anticipates the claims by interpreting either the plain language of the claims or what is disclosed by Levine in a manner that is either overly abstract or just plain wrong. Appellant appreciates an examiner's obligation to give patent claims a broad reading in order to judge their patentability in view of the prior art. It goes too far, however, when the reading of the words in a claim is at odds with their normal usage in the English language, contrary to the description of the claimed subject matter in the specification, and renders the claim recitations into nonsense.

The Answer states on page 3 that:

> As related to the first sensing channel, according to the specification, one or more sensing channels may be recorded, and there is not just one sensing channel, but rather four sensing channels: an atrial channel (31, 33A, 33B), a first ventricular channel (41,43A, 43B), a second ventricular channel (51,53A, 53B), and an evoked response channel (21, 23, 70) (page 6, lines 3-6; page 8, lines 4-22). The discussion of claim 1 and 11 is misleading.

As stated in the specification (page 6, lines 24-26), "the present invention may be incorporated into any cardiac device with the capability of sensing cardiac electrical activity, including devices for monitoring only and those for delivering therapy in the form of electrical

stimulation to the heart." The description of a device having four sensing channels was for illustrative purposes only. In any event, the claims are clearly supported by the specification and have not been rejected under section 112.

Also on page 3, the Answer states that "the Examiner is unable to find in the instant specification, the discussion of the Q-T interval at the bottom page 4 in the corrected Section V. of the Appeal Brief filed 3/30/09." The discussion in the Appeal Brief of the Q-T interval was only meant to give an example of a type of morphology change and is not something that is being specifically claimed.

Appellant asserted in the Appeal Brief that neither the Levine nor the incorporated Snell reference describe a system component configured to compute an average electrogram from a plurality of electrograms taken over some period of time (i.e., over the discrete time interval). The Examiner disagrees, stating that:

> Levine et al. disclose using averaging software to combine the data from the four separate data streams, four separate IEGM channels, read to be electrograms taken over some period of time (i.e., over the discrete time intervals), in to a single IEMG signal (column 15, lines 57-66). In addition, Levine et al. teach computation and displaying of real-time and recorded data (column 15, lines 5-13).

The type of average electrogram recited by claims 1 and 11 is a time average, not an average of electrograms recorded from different locations at the same time as disclosed by Levine. This is made clear by the description of the subject matter in the specification as well as the claim language itself which refers to a "time average." Claims 1 and 11 also recite only one sensing channel and therefore cannot be read such that the recited average electrogram encompasses an average of electrograms taken from different locations.

Appellant asserted in the Appeal Brief that neither the Levine nor the incorporated Snell reference describe a system component configured to compute a plurality of average electrograms for a plurality of discrete time intervals, referred to as representative electrograms. The Examiner again disagrees, stating that:

> Levine et al. disclose using averaging software to combine the data from the four separate data streams, four separate IEGM channels, read to be

> electrograms taken at different times, a representative electrogram that represents the different discrete time intervals, into a single IEMG signal (column 15, lines 57-66). Snell et. al is cited to teach data sampling rate, sampling periods and averaging of stored event data in each of the sampling periods, hence producing a plurality of average electrograms for a plurality of discrete time interval, referred to as representative electrograms (column 17,line 60 - column 18, line 3; column 22, lines 5-16).

Here, the Examiner is somehow interpreting the four separate IEGM signals from different locations described by Levine as "electrograms taken at different times." Levine, however, only describes averaging four separate IEGM signals that are recorded at the same time. Obviously, as the device described by Levine operates over time, such average IEGM signals would be computed at different times. Levine neither teaches nor suggests, however, computing and storing a plurality of average electrograms that represent different periods of time, referred to in claim 1 as the plurality of discrete time intervals. Although claim 1 does not specifically recite that the representative electrograms are stored, that is necessarily implied by the subsequent recitation relating to their aggregate display.

Appellant asserted in the Appeal Brief that neither the Levine nor the incorporated Snell reference describe a system component configured to aggregately display a plurality of electrograms, each of which having been recorded during different periods of time (i.e., the representative electrograms that represent the different discrete time intervals). The Examiner again disagrees, stating that:

> Levine et al. discloses a system component, an external programmer with a display (figure 3 - 102, figure 7 - 316) configured to aggregately display a plurality of electrograms (figure 10; column 16, lines 35-37), the aggregate display read as the pulling together and graphical display of the three cardiac signals at the same time, each have been recorded (at) different period of time (i.e., the representative electrogram that represent the different discrete time intervals), the atrial IEMG signal, the ventricular IEMG signal and a surface EMG complex accepted to be recorded at different periods of time as these heart events are interrelated and occur at different times during the cardiac heart beat cycle. In addition, Levine et al. teach computation and displaying of real-time and recorded data (column 15, lines 5-13).

The Examiner appears to be saying that atrial, ventricular, and surface IEMG signals recorded by the Levine device and then simultaneously displayed are IEMG signals that are recorded at

different times because they are interrelated heart events that occur at different times during the cardiac cycle. Appellant finds this incomprehensible. An electrogram signal is a recording of the electrical potential generated by the heart over time as the heart depolarizes and repolarizes during each cardiac cycle. An electrogram is not a "heart event," and electrograms recorded from different locations do not "occur at different times during cardiac heart beat cycle." The Answer goes on to state with respect to this issue:

> From a different point of view, Levine et al. disclose using averaging software to combine the data from the four separate data streams, four separate IEGM channels, read to be electrograms recorded at different times, a representative electrogram that represents the different discrete time intervals, into a single IEMG signal (column 15,lines 57-66). Levine et al. discloses a system component, an external programmer with a LCD display (figure 3 - 102; figure 5 - 200, 214; figure 7 - 31 6; column 3, lines 6-24;column 10, lines 29-33), configured to aggregately display a plurality of electrograms as a single electrogram, read as the representative electrogram, that represents the different discrete time intervals. In addition, Levine et al. teach computation and displaying of real-time and recorded data (column 15, lines 5-13).

The Examiner again incorrectly characterizes the four separate IEGM signals that are combined into a single IEGM signal by the Levine device as electrograms recorded at different times.

Appellant asserted in the Appeal Brief that neither the Levine nor the incorporated Snell reference describes either 1) averaging electrograms recorded at different times (i.e., a time average), or 2) simultaneously displaying electrograms recorded at different times, whether averaged or not, in graphical form as indexed by time. In response, the Examiner makes statements similar to those quoted above that argue that the electrograms recorded from different locations and then averaged together by the Levine device are electrograms recorded at different times. That is simply wrong. Levine describes the averaging together of electrograms recorded at the same time from different locations. Furthermore, it would make no sense to average together electrograms recorded from different locations at different times.

Appellant asserted in the Appeal Brief that neither the Levine nor the Snell reference describes a system component for computing an average of electrograms recorded while the heart rate is within a particular range as recited by claim 11. In response, the Examiner states

that "(s)ince 'a particular range' is not further defined, the range could be any range, hence it is accepted Levine et al. teaches a system component for computing an average electrogram recorded while the heart rate is within a particular range." Obviously, any electrogram is recorded while is heart rate is within *some* heart rate range. Claim 11, however, states that the representative electrogram for a particular heart rate range is computed from one or more electrograms recorded *only* when the patient's heart rate is within that particular heart rate range, where each such particular heart rate range is selected from the recited plurality of heart rate ranges. Appellant also reiterates that the average of electrograms recited by claim 11 is a time average, not an average of electrograms taken from different locations.

Appellant asserted in the Appeal Brief that neither the Levine nor the Snell reference describes the following elements recited by claim 11: 1) a system component for computing a plurality of representative electrograms where each such representative electrogram is an average of electrograms recorded while the heart rate is within a different heart rate range, or 2) a system component configured to simultaneously display a plurality of electrograms, whether averaged or not, recorded while the heart rate is within different heart rate ranges and to index the displayed electrograms by heart rate. The Examiner responds by stating the following:

> In response to the Appellants argument that the references fail to show a certain features of the Applicant's invention, it is noted that the feature upon which the Appellant relies (i.e., "the heart rate is within a different heart rate range") is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Since the limitation of "the heart rate is within a different heart rate range" is not a limitation found in the claims currently being processed, the Examiner will not comment further on this argument.

Claim 11 recites that the device controller is programmed to "generate representative electrograms for each of a plurality of heart rate ranges." When read in light of the specification, the claim clearly refers to different heart rate ranges. It is not reading limitations from the specification into a claim when context supplied from the specification is necessary for the claim to make sense. Furthermore, in normal English language, when one refers to a plurality of quantitative measures such as heart rate ranges, it is implied that the

measures are different. For example, a ten-speed bicycle in which all the speeds are the same is not a ten-speed bicycle but is only a one-speed bicycle. Similarly, a plurality of heart rate ranges that are all the same is not a plurality of heart rate ranges but is only a single heart rate range. Although Appellant would have had no objection to explicitly stating that the heart rate ranges are different in claim 11, that limitation is necessarily implied by the claim language as is.

Appellant previously stated that the recitations of the dependent claims, such as using different shades or colors for the different representative electrograms as recited by claims 8 and 17, are neither taught nor suggested by the cited references in the context of their combination with the subject matter of either claim 1 or claim 11. Appellant described the Palmer reference as disclosing the use of color coding for signifying different amplitude values of displayed variables. That disclosure is found at col. 2, lines 13-18 of the reference. Appellant reiterates that such a color coding scheme is not in any way similar to the use of different colors for displaying representative electrograms in order to indicate the time period or heart rate range represented by the electrograms as recited by claims 8 and 17.

CONCLUSION

The pending claims subject to this appeal are believed patentable. Appellant respectfully submits that the claims are in condition for allowance and requests the Board issue an order to withdraw the rejections.

Respectfully submitted,

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Date September 9, 2009 By / J. Kevin Parker /
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